

REMARKS

Applicants respectfully request entry of amendments to claims 12 and 16, and cancellation of claim 13. Support for the amendments can be found throughout the specification, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 12, and 14-19 are in condition for allowance, or are in better condition for presentation on appeal, and respectfully request that the claims as amended be entered.

Priority

The Examiner alleges that prior-filed application no. 08/439962 does not provide support for one or more claims of this application, in particular detection of hypermethylation of CpG islands in the first exon. Applicants have amended independent claim 12 herein to remove this limitation, as detailed below. It is believed that application no. 08/439962 supports amended claim 12.

Oath/Declaration

The Examiner objected to the oath, stating that it should be amended to indicated that the instant application is a CIP of application 08/497535. Applicants disagree that an amended oath is needed.

A declaration was filed on September 3, 2003 along with the filing of the application. The declaration was filed with the parent application, application no. 08/439,962. The current application is a continuation of application no. 09/225,904, which is a divisional application of application no. 08/497,535, which is a continuation-in-part of application no. 08/439,962.

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 12-19 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Applicants traverse the rejection as it might apply to the amended claim 12, including claims dependent therefrom, for the reasons given below.

Claim 12 no longer recites “steps for detecting hypermethylation” so this aspect of thee rejection is rendered moot.

Regarding the phrase “detecting a first amplification product comprising exon 2 of the p16 gene in the absence of identifying a second amplification product comprising exon 1 of the p16 gene, wherein hypermethylation of a 5’ CpG island in the first exon of the p16 gene is associated with the presence of the truncated product” as recited in claim 12, while Applicants do not acquiesce to the reasoning offered in the Office Action, in order to expedite prosecution toward allowance, claim 12 has been amended to recite that the first amplification product contains exon 2.

Regarding claim 13 and 16, while Applicants do not acquiesce to the reasoning offered in the Office Action, in order to expedite prosecution toward allowance, claim 13 has been canceled and claim 16 amended to change the dependency of the claim.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 12-19 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention.

Enabled subject matter

The Examiner notes that the specification is “enabling for a method comprising: a) contacting a sample with the oligonucleotide primer which anneals and amplifies the region of the p16 gene consisting of exon 1 and a primer which anneals and amplifies the region of the p16 gene consisting of exon 2 under conditions for primer extension and producing an amplified product b) contacting the amplified product with the primer which binds to and extends the 5’ ALT gene c) detecting the presence of a amplification production [sic] containing the amplified portions of exon 1 and 2 or detecting the presence of the amplification product of only exon 2 when the 5’ ALT gene is present.” (Office Action, pages 5-6.)

In an effort to advance prosecution of the present application, claim 12 has been amended to incorporate limitations that the Examiner suggests enable the subject matter of the claims. Additionally, the claim has been amended to clarify that the claimed method is directed towards detecting a cell proliferative disorder. This amendment has support in the specification in, for example, Example 4, Example 6, Example 8 and Example 11; therefore, the amended elements do not add new matter. Claim 13 has been cancelled.

In light of the amendments, withdrawal of rejection of claims 12, and 14-19 under 35 U.S.C. §112, first paragraph is respectfully requested.

In re Application of:
Sidransky and Baylin
Application No.: 10/659,519
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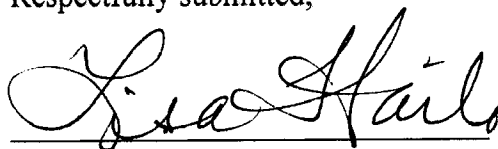
PATENT
Attorney Docket No. JHU1300-6

Conclusion

Applicants submit that pending claims 12-19 are in condition for allowance, or are in better condition for appeal. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fees are deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,

A handwritten signature in cursive script, reading "Lisa A. Haile". The signature is written in dark ink and is positioned above the printed name and contact information.

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